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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Submission for OMB review; 30-day comment request

Prevalence, Incidence, Epidemiology and Molecular Variants of HIV in Blood Donors in Brazil (NHLBI)

SUMMARY: Under the provisions of Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the National Heart, Lung, and Blood Institute (NHLBI), the National Institutes of Health (NIH) has submitted to the Office of Management and Budget (OMB) a request for review and approval of the information collection listed below. This proposed information collection was previously published in the FR in Volume 79 on December 31, 2014 on page 78876 and allowed 60-days for public comment. One public comment was received that was a personal opinion regarding conducting research about the Brazil blood donation system. The purpose of this notice is to allow an additional 30 days for public comment. The National Institutes of Health may not conduct or sponsor, and the respondent is not required to respond to, an information collection that has been extended, revised, or implemented on or after October 1, 1995, unless it displays a currently valid OMB control number.

DIRECT COMMENTS TO OMB: Written comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated

response time, should be directed to the: Office of Management and Budget, Office of Regulatory Affairs, OIRA_submission@omb.eop.gov or by fax to 202-395-6974, Attention: Desk Officer for NIH.

COMMENTS DUE DATE: Comments regarding this information collection are best assured of having their full effect if received within 30 days of the date of this publication.

FOR FURTHER INFORMATION: To obtain a copy of the data collection plans and instruments or request more information on the proposed project contact: Simone Glynn, MD, Project Officer/ICD Contact, Two Rockledge Center, Suite 9142, 6701 Rockledge Drive, Bethesda, MD 20892, or call 301- 435-0065, or E-mail your request, including your address to: glynnsa@nhlbi.nih.gov. Formal requests for additional plans and instruments must be requested in writing.

PROPOSED COLLECTION: Prevalence, Incidence, Epidemiology and Molecular Variants of HIV, in Blood Donors in Brazil 0925-0597, expiration date, July 31, 2015, Extension, the National Heart, Lung, and Blood Institute (NHLBI), the National Institutes of Health (NIH).

Need and Use of Information Collection: Establishing and monitoring viral prevalence and incidence rates, and identifying behavioral risk behaviors for HIV infection among donors are critical steps to assessing and reducing risk of HIV transmission through blood transfusion. Detecting donors with recently acquired HIV infection is particularly critical as it enables characterization of the viral subtypes currently transmitted within the screened population. In addition to characterizing genotypes of recently infected donors for purposes of blood safety, molecular surveillance of incident HIV infections in blood donors serves important public health roles by identifying new HIV infections for anti-retroviral

treatment, and enabling documentation of the rates of primary transmission of anti-viral drug resistant strains in the community. This study is a continuation of the current protocol that is approved by OMB, which expires on July 31, 2015, includes both a prospective surveillance and a case study designed to enroll eligible HIV seropositives detected at four participating blood centers in Brazil.

This project is being conducted at the same four blood centers in Brazil, located in the cities of Sao Paulo, Recife, Rio de Janeiro and Belo Horizonte, but this time restricted to the study of HIV-positive subjects.

The primary study aims are to continue monitoring HIV molecular variants and risk behaviors in blood donors in Brazil, and to evaluate HIV subtype and drug resistance profiles among HIV-positive donors according to HIV infection status (recent versus long-standing infection), year of donation, and site of collection. Additional study objectives include determining trends in HIV molecular variants and risk factors associated with HIV infection by combining data collected in the previous REDS-II project with that which will be obtained in the planned research activities.

Given the initiation of NAT testing for HIV (and HCV) in Brazil, it will be important to continue to collect molecular surveillance and risk factor data on HIV infections. especially now that infections that might not have been identified by serology testing alone could be recognized through the use of NAT. NAT-only infections represent very recently acquired infections. The NAT assay will continue to be used at the four REDS-III blood centers in Brazil during the research activities. In addition, in order to distinguish between recent seroconversion and long-standing infection, samples from all HIV antibody dual reactive donations and/or NAT positive donations will continue to be tested by the Recent Infection Testing Algorithm (RITA) which is based on use of a sensitive/less-sensitive enzyme immunoassay ("detuned" Enzyme Immunoassay). RITA testing will continue to be performed by the Blood Systems Research Institute, San Francisco, California, USA, which is the REDS-III Central Laboratory.

Since Dec 2012, the study has enrolled 223 HIV-positive donors (51 at Hemorio-Rio de Janeiro, 38 at Hemominas-Minas Gerais, 67 at Hemope-Pernambuco and 67 at Fundacao Pro-Sangue-Sao Paulo)

with a target enrollment of 500 by 2017. It is important to continue the study and enroll more HIV infected donors to inform trend analyses. Preliminary evaluation of data has shown that respondent donors are completing the entire questionnaire including information about their risk behaviors. According to the Brazilian guidelines, blood donors are requested to return to the blood bank for HIV confirmatory testing and HIV counseling. Donors are invited to participate in the study through administration of informed consent when they return for HIV counseling. Once informed consent has been administered and enrollment has occurred, participants are asked to complete a confidential self-administered risk factor questionnaire by computer. In addition, a small blood sample is collected from each HIV-positive participant to be used for the genotyping and drug resistance testing. The results of the drug resistance testing are communicated back to the HIV-positive participants during an in-person counseling session at the blood center. For those individuals who do not return for confirmatory testing, the samples will be anonymized and sent to the REDS-III Central Laboratory to perform the recent infection testing algorithm (RITA).

This research effort will allow for an evaluation of trends in the trafficking of non-B HIV subtypes and rates of transmission of drug resistant viral strains in low risk blood donors. These data could also be compared with data from similar studies in higher risk populations. Monitoring drug resistance strains is extremely important in a country that provides free anti-retroviral therapy for HIV infected individuals, many of whom have low level education and modest resources, thus making compliance with drug regimens and hence the risk of drug resistant HIV a serious problem. It is worth noting that Brazil is the first developing country to implement early treatment initiation for all individuals living with HIV/AIDS irrespective of CD4 count; this new universal treatment policy went into effect in 2014.

Findings from this study will be compared to trends in prevalence, incidence, and molecular variants from studies of the general population and high risk populations in Brazil, thus allowing for broader and more effective monitoring of the HIV epidemic in Brazil, as well as assessment of the impact

of donor selection criteria on these parameters. We also propose to continue to examine trends in risk behaviors by comparing the data previously collected to the data we plan to collect for the next three year period. This will allow for extended trend analyses over a 10-year period that complements similar monitoring of HIV prevalence, incidence, transfusion risk and molecular variants in the USA and other funded international REDS-III sites in South Africa and China, thus allowing direct comparisons of these parameters on a global level.

OMB approval is requested for 3 years. There are no costs to respondents other than their time. The total estimated annualized burden hours are 40.

Form Name	Type of Respondent	Number of Respondents	Number of Responses per Respondent	Average Burden Per Response (in hours)	Total Annual Burden Hour
Risk Factor Informed Consent	Adult Donors	100	1	5/60	8
Risk Factor Assessment	Adult Donors	100	1	19/60	40

Dated: March 11, 2015.

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National Institutes of Health.

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